

Docket No.: 58511-015

AF 2166
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of

Christian MAYAUD

Serial No.: 09/121,596

Filed: July 24, 1998

Group Art Unit: 2166

Examiner: S. Rimell

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Technology Center 2100

OF COMPUTERIZED PRESCRIPTION SYSTEM FOR GATHERING AND PRESENTING
INFORMATION RELATING TO PHARMACEUTICALS (AS AMENDED)

TRANSMITTAL OF APPEAL BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

Submitted herewith in triplicate is Appellant's Appeal Brief in support of the Notice of Appeal filed January 15, 2002. Please charge the Appeal Brief fee of \$320.00 to Deposit Account 500417.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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APPEAL BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This Appeal Brief is submitted in support of the Notice of Appeal filed January 15, 2002, from the final rejection of the Examiner dated October 15, 2001.

REAL PARTY IN INTEREST

The real party in interest is ANDRX CORPORATION.

RELATED APPEALS AND INTERFERENCES

The undersigned is aware of no related appeals or Interferences which would impact a decision in this Appeal nor which would be impacted by a decision in this Appeal.

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STATUS OF CLAIMS

Claims 70, 72-92 and 94-102 are pending in the application. Claims 1-69, 71 and 93 have been cancelled. Claims 70, 72-92 and 94-102 stand rejected.

STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the final rejection.

SUMMARY OF INVENTION

The invention is directed to a computerized prescription system for gathering and presenting information relating to pharmaceuticals. More specifically, the invention is directed to techniques for utilizing a computerized prescription system where a user computer has a graphical user interface that permits the capturing of prescription information, provides access to information about a patient's prescription history, about pharmaceuticals arranged by medical conditions and about properties of pharmaceuticals. The user computer can communicate with other computers and specifically other computers of a group consisting of a health maintenance organization, an insurance company, a direct benefit plan, a pharmacy run by a different organization than the organization running the user computer, laboratory and a physician practice. In short, the user computer can not only capture prescriptions in the context of all relevant information about a patient's history or pharmaceuticals that may be prescribed and can communicate with pharmacies and organizations that might pay for, fill or document the prescriptions.

The invention is also directed to a computer implemented method of creating a prescription using a personal digital assistant, formatting the information for communications and sending the prescription information to a pharmacy located remotely from the facility at which the prescription

information is captured.

Another aspect of the invention is related to a method of compiling a patient record by interrogating remote databases and assembling patient information into a chronologically current version of the patient's medical history.

Another aspect of the invention is directed to a computer having a graphical user interface which permits capture of prescription information and provides access to all of information about a patient's medical history, information about therapeutic agents and information about individual prescriber activity.

Other aspects of the invention are directed to computer program products corresponding generally to the descriptions given above.

ISSUES

The following issues are presented by this Appeal:

1. Whether the Examiner erred in rejecting claims 70, 72-83, 91-92, 94-99 and 101-102 under 35 U.S.C. 102(e) as anticipated by Schrier et al.
2. Whether the Examiner erred in rejecting claims 84-90 and 100 under 35 U.S.C. 103 is unpatentable of Schrier et al. in view of Ballantyne et al.

GROUPING OF CLAIMS

Each claim under rejection is argued separately and no claims stands or falls with any other claim.

THE ARGUMENT

The Examiner erred in rejecting claims 70, 72-83, 91-92, 94-99 and 101-102 under 35 U.S.C. 102(e) as anticipated by Schrier et al. The Examiner acknowledges that the computer in Schrier is connected to a network of computers "as part of a hospital or other type of clinical setting." The Examiner then goes on to say that "No patentable weight is attributable to who runs or operates the other computers that the computer (112) communicates with, since this has no bearing on the physical structure of the system." The Examiner may not ignore claim limitations, especially since the recent decision of the Court of Appeal for the Federal Circuit in Docket Number 00-1158, decided January 18, 2002 (In re Lee).

Claims 70 and 99 require that the user computer selectively communicates "with one or more other computers run respectively by or on behalf of one or more of a group consisting of (a) the Health Maintenance Organization, (b) an insurance company, (c) a drug benefit plan, (d) a pharmacy run by a different organization than the organization running the user computer, (e) a laboratory, and (f) a physician practice." The Schrier reference does not teach or suggest any of these limitations.

— Claim 72 is acknowledged to stand or fall with claim 70.

Claim 73 is dependent upon claim 72 and is allowable for the reasons given with respect to claim 70. Further, claim 73 requires "gathering information from more than one of said one or more other computers and presents that information to a user through said graphical user interface." This is not taught or suggested by Shrier.

Dependent claim 74 depends upon claim 73 and is allowable for the reasons given with respect to claim 73. In addition, claim 74 requires "gathering information from more than one of said one or more other computers and compiling that information into a prescription history for a patient." This is not taught or suggested by Shrier.

Claim 75 is dependent upon claim 73 and is allowable for the reasons given with respect to claim 73. In addition, claim 75 requires "gathering information for more than one of said one or more other computers and compiling that information into said information about pharmaceuticals." It is not taught or suggested by Shrier.

Claim 76 is dependent upon claim 73 and is allowable for the reasons given with respect to claims 73. In addition, claim 76 requires "gathering information for more than one of said one or more other computers and compiling that information into said information about the properties of pharmaceuticals." That is not taught or suggested by Shrier et al.

Claim 77 is dependent from claim 70 and is allowable for the reasons given with respect to claim 70. In addition, claim 77 requires "permitting a user to send a prescription directly to a pharmacy to be filled...using said graphical user interface." This is not taught or suggested by Shrier.

Claim 78 is dependent upon claim 70 and is allowable for the reasons given with respect to claim 70. In addition, claim 78 requires a step of "selectively arranging information about pharmaceuticals in at least two of" specified orderings.

— Claims 79 and 80 are both dependent upon claim 70 and are each allowable for the reasons given with respect to claim 70. In addition, the claims require, respectively, arranging information about pharmaceuticals "in order of the body system treated by the pharmaceuticals" and arranging information about pharmaceuticals "by drug category." The reference applied by the Examiner does not teach or suggest either of these limitations.

Claim 81 is dependent upon claim 70 and is allowable for the reasons given with respect to claim 70. In addition, claim 81 requires that "when a pharmaceutical is prescribed for a condition, and the pharmaceutical is not the best first line agent for treatment of that condition, suggestion an alternative pharmaceutical to be prescribed instead." This is not taught or suggested by the references.

Claim 82 is dependent upon claim 81 and is allowable for the reason given with respect to claim 81. In addition, claim 82 requires "retrieving guidelines relating to the use of said alternative pharmaceutical using said graphical user interface." This is not taught or suggested by the reference.

Claim 83 is dependent upon claim 70 and is allowable for the reasons given with respect to claim 70. Further, claim 83 requires "arranging information about a patient's prescription history by condition for which a prescription was written." Shrier et al. does not teach or suggest this limitation.

Independent claim 91 requires "interrogating databases located remotely from said location expected to contain information about a patient based on a patient's relationship with the provider of that database and assembling patient information into a chronologically current version of said patient's medical history." This is not taught or suggested by Shrier et al.

Claim 92 is dependent upon claim 91 and is allowable for the reasons given with respect to claim 91. Claim 92 further requires "discarding said current version of said patient's medical history without creating a file copy." This is not taught or suggested by the reference.

Independent claim 94 requires a "user computer and a graphical user interface" and includes the step of "permitting capture of prescription information and selectively accessing... information about individual prescriber activity, from only databases located remotely from the location from said user computer." Schrier et al. do not describe a graphical user interface which permits access to information about individual prescriber activity. Although it may record the fact that a particular prescriber did fill out a particular prescription, the user interface does not provide access to it as required by claim 94. Further, in Schrier, the information is not obtained from offsite databases. Independent claim 94 also requires "permitting capture prescription information and providing access to all of (1) information about a patient's medical history, (2) information about therapeutic agents and (3) information about individual prescriber activity." The reference applied by the Examiner does not teach or suggest these

limitations.

Claim 95 is dependent upon claim 94 and is allowable for the reasons given with respect to claim 94. In addition, claim 95 requires that "said information about individual prescriber activity is stored on said user computer and also on another computer." This is not taught or suggested by the reference.

Claim 96 is dependent upon claim 94 and is allowable for the reasons given with respect to claim 94. In addition, claim 96 requires that "information about a patient's medical history includes identification of one or more prescriptions and an identification of a person who prescribes said one or more prescriptions." This is not taught or suggested by the reference.

Claim 97 is dependent upon claim 96 and is allowable for the reasons given with respect to claim 96. In addition, claim 97 requires that the "identification of a person who prescribes said one or more prescriptions includes identification of how to contact said person." This is not taught or suggested by the reference.

Claim 98 is dependent upon claim 94 and is allowable for the reason's given with respect to claim 94. In addition, claim 98 requires that the "graphical user interface includes providing suggestions to a provider for dosages based on said patient's medical history." This is not taught or suggested by the references.

Independent claim 99 is a computer program product claim that requires that there be "instructions for capturing prescription information and providing access to all of" three categories of specific information and "instructions to communicate with one or more other computers run respectively by or on behalf of one or more of a group consisting of another specified list of computers specified mainly by type of organization which owns them.

- The Examiner has chosen to ignore these limitations. The reference does not teach or suggest these limitations.

Independent claim 101 is a computer program product claim requiring "instructions for interrogating databases remotely located from a computer running said computer program" and "expected to contain information about a patient based on a patient's relationship with a provider of that database; and for assembling patient information into a chronologically current version of said patient's medical history." The reference does not teach or suggest assembling information from diversified databases into a chronologically current version of said patient's medical history." Independent claim 101 also requires "a computer program... containing instructions for interrogating databases remotely located from a computer running said computer program expected to contain information about a patient based on a patient's relationship with the provider of that database." Schrier does not teach or suggest communicating with said offsite databases and certainly not with respect to databases "expected to contain information about a patient based on a patient's relationship with the provider of that database."

Independent claim 102 is a computer program product claim requiring instructions for implementing a graphical user interface permitting capture of prescription information and providing access to certain specified categories of information including "information about individual prescriber activity." It is not taught or suggested by the references.

Thus, each of the independent claims rejected by the Examiner as anticipated by Schrier et al., contain limitations which are neither taught nor suggested by Schrier et al. Accordingly, Applicant respectfully requests that the Examiner withdraw these objections.

The Examiner has thus failed to establish a *prima facie* case of anticipation of each of these claims.

The Examiner also erred in rejecting claims 84-90 and 100 under 35 U.S.C. 103 as unpatentable over Shrier et al. in view of Ballantyne et al.

The Examiner states:

"Ballantyne et al. discloses the usage of personal digital assistants (10) as a user computer in a telemedicine environment. It would have been obvious to one of ordinary skill in the art to substitute a personal digital assistant for the user computer (112) in Schrier et al. so as to allow the user the advantage of mobility, as taught by Ballantyne et al."

There are several problems with the Examiner's analysis. First, Ballantyne does not disclose the use of "personal digital assistants." The term Ballantyne uses is "personal data assistant."

In the application under examination, the specification, beginning on page 19, line 23, recites the following:

"The prescription management system shown in this embodiment of the invention has been designed for implementation on physically compact, portable, user-interface devices, such as small portable personal computers, especially hand held devices known as personal digital assistants."

An example of a personal digital assistant is given in the specification at page 8, line 3 et seq. where the "Apple NEWTON" is referenced. The Apple Newton was a handheld device similar to the Palm™ brand of personal digital assistants that are currently popular.

The personal data assistant of Ballantyne et al. has considerably different characteristics than the "personal digital assistant" of this application. In Ballantyne et al., the "personal data assistant" is designed to "replace the paper clip board and allow the user to interface to an electronic database." See column 13, lines 40, 43 and 44. Further, the "personal data assistant" of the Ballantyne reference are maintained at the nursing station and are not personal to the individual who uses the "personal data assistant." See column 12, line 12, et seq. Like the clipboard it replaces, the "personal data assistant" of Ballantyne et al. is used by a plurality of different individuals. It is therefore quite different from the

"personal digital assistant" of the application which is truly a device personal to an individual.

It is also quite clear that one could not substitute a "personal digital assistant for the user computer (112) in Schrier et al." This is because personal digital assistants, even advanced personal digital assistants, lack the computing power, by design, to implement the functionality of the user computer 112 in Schrier et al.

Finally, if one were to substitute the "personal data assistant" of Ballantyne et al. for the user computer of Schrier et al., there would be no "advantage of mobility" since the personal data assistant of Ballantyne et al. is designed to be maintained in the nurses station and not to travel with a particular individual.

Claim 84 is dependent upon claim 70 and is allowable for the reasons given with respect to claim 70. In addition, claim 84 requires that the user computer is a "personal digital assistant." As discussed above, neither of the references applied by the Examiner against this claim teach or suggest this limitation.

Independent claim 85 requires "capturing prescription information using a computer interface of a personal digital assistant; formatting said prescription information for communications; and sending said prescription formation to a pharmacy located remotely from a facility at which said prescription information is captured over a communication link to be filled." As noted above, Ballantyne does not disclose a "personal digital assistant" as required by this claim. Further, Ballantyne does not send the prescription "to a pharmacy located remotely from a facility at which said prescription information is captured over a communication link to be filled."

Claim 86 is dependent from claim 85 and is allowable for the reasons given with respect to claim 85. In addition, claim 86 requires that the "prescription information includes the condition to be treated by the prescribed item." This is not shown by the references.

Claim 87 is dependent from claim 85 and is allowable for the reasons given with respect to claim 85. In addition, claim 87 requires that the "prescription information is selected from a predefined list." This is not taught or suggested by the references.

Claim 88 is dependent upon claim 87 and is allowable for the reasons given with respect to claim 87. In addition, claim 88 requires that the "predefined list is arranged in order of frequency of prescription for a specified condition to be treated." This is not taught or suggested by the references.

Claim 89 is dependent upon claim 87 and is allowable for the reasons given with respect to claim 87. In addition, claim 87 requires that the "predefined list is arranged in order of cost." This is not taught or suggested by the references.

Claim 90 is dependent upon claim 87 and is allowable for the reasons given with respect to claim 87. In addition, claim 90 requires that the "predefined list is arranged in order of therapeutic preference according to drug formulary guidelines." This not taught or suggested by the references.

Independent claim 100 is a computer program product claim requiring instructions "for capturing prescription information using a computer interface of a personal digital assistant, for formatting said prescription information... and sending said prescription formation to a pharmacy located remotely from said personal digital assistant over a communication link to be filled." As noted above, Ballantyne does not teach or disclose personal digital assistant. Rather, Ballantyne uses a "personal data assistant" which, as noted from the specification of the Ballantyne et al. patent has characteristics considerably different from a personal digital assistant as that term is used in the application on appeal.

The Examiner has made no findings with respect to why it would obvious to combine the teachings of Ballantyne et al. with Shrier et al. See *In re Lee*, *ibid*.

Further, even if Ballantyne et al. were combined with Shrier et al. it would only result in a personal data assistant being linked by infrared to a patient care station and there would not be the mobility permitted under the claimed invention.

Thus, the Examiner has failed to establish a *prima facie* case of obviousness.

CONCLUSION

Applicant respectfully requests the Board of Patent Appeals and Interferences to reverse the Examiner's rejections because the Examiner has failed to establish a *prima facie* case of either anticipation or obviousness and because the references do not show Applicant's claimed invention.

Respectfully submitted,

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APPENDIX

70. A method of using a computerized prescription system, having

at least one user computer and a graphical user interface, the method comprising the steps of:

a. permitting capture of prescription information and

b. selectively providing access to all of (1) information about a patient's prescription history, (2) information about pharmaceuticals arranged by medical conditions for which the pharmaceuticals are suitable for treating, and (3) information about the properties of pharmaceuticals using said user interface, and

c. selectively communicating with one or more other computers run respectively by or on behalf of one or more of a group consisting of (a) a Health Maintenance Organization, (b) an insurance company, (c) a drug benefit plan, (d) a pharmacy run by a different organization than the organization running the user computer, (e) a laboratory, and (f) a physician practice.

73. The method of claim 72, further comprising the step of gathering information from more than one of said one or more other computers and presents that information to a user through said graphical user interface.

74. The method of claim 73 further comprising the step of gathering information from more than one of said one or more other computers and compiling that information into a prescription history for a patient.

75. The method of claim 73, further comprising the step of gathering information from more than one of said one or more other computers and compiling that information into said information about

pharmaceuticals.

76. The method of claim 73, further comprising the step of gathering information from more than one of said one or more other computers and compiling that information into said information about the properties of pharmaceuticals.

77. The method of claim 70, further comprising the step of permitting a user to send a prescription directly to a pharmacy to be filled over said communications medium, using said graphical user interface.

78. The method of claim 70, further comprising the step of selectively arranging information about pharmaceuticals in at least two of (1) the order of frequency with which pharmaceuticals are prescribed by a user, (2) in alphabetical order, (3) in order of condition treated and (4) in order of pharmaceuticals prescribed for a particular patient.

79. The method of claim 70, further comprising the step of arranging information about pharmaceuticals in order of the body system treated by the pharmaceuticals.

80. The method of claim 70, further comprising the step of selectively arranging information about pharmaceuticals by drug category.

81. The method of claim 70, further comprising the step of when a pharmaceutical is prescribed for a condition, and the pharmaceutical is not the best first line agent for treatment of that condition,

suggesting an alternative pharmaceutical to be prescribed instead.

82. The method of claim 81, further comprising the step of retrieving guidelines relating to the use of said alternative pharmaceutical using said graphical user interface.

83. The method of claim 70, further comprising the step of said arranging information about a patient's prescription history by condition for which a prescription was written.

84. The method of claim 70, in which said user computer is a personal digital assistant.

85. A computer implemented method of creating a prescription, comprising the steps of:

- a. capturing prescription information using a computer interface of a personal digital assistant;
- b. formatting said prescription information for communications; and
- c. sending said prescription formation to a pharmacy located remotely from a facility at which said prescription information is captured over a communication link to be filled.

86. The method of claim 85, in which said prescription information includes the condition to be treated by the prescribed item.

87. The method of claim 85, in which said prescription information is selected from a predefined list.

88. The method of claim 87, in which said predefined list is arranged in order of frequency of

prescription for a specified condition to be treated.

89. The method of claim 87, in which said predefined list is arranged in order of cost.

90. The method of claim 87, in which said predefined list is arranged in order of therapeutic preference according to drug formulary guidelines.

91. A method of compiling a patient record at a location, comprising the steps of:

- a. interrogating databases located remotely from said location expected to contain information about a patient based on a patient's relationship with the provider of that database; and
- b. assembling patient information into a chronologically current version of said patient's medical history.

92. The method of claim 91, further comprising the step of discarding said current version of said patient's medical history without creating a file copy.

94. A method of using a computerized prescription system, having

at least one user computer, said user computer having a graphical user interface comprising the steps of:

- a. permitting capture of prescription information and
- b. providing access to all of (1) information about a patient's medical history, (2) information about therapeutic agents and (3) information about individual prescriber activity, wherein the information from only databases located remotely from the location of said user computer.

99. A computer program product, comprising:

a. a memory medium; and

b. a computer program stored on said memory medium, said computer program containing instructions for capturing prescription information and providing access to all of (1) information about a patient's prescription history, (2) information about pharmaceuticals arranged by medical conditions for which the pharmaceuticals are suitable for treating, and (3) information about the properties of pharmaceuticals, wherein said computer program comprises further instructions to communicate with one or more other computers run respectively by or on behalf of one or more of a group consisting of (a) a Health Maintenance Organization, (b) an insurance company, (c) a drug benefit plan, (d) a pharmacy run by a different organization than the organization running the user computer, (e) a laboratory, and (f) a physician practice.

100. A computer program product, comprising:

a. a memory medium; and

b. a computer program stored on said memory medium, said computer program containing instructions for capturing prescription information using a computer interface of a personal digital assistant, for formatting said prescription information for communications; and sending said prescription formation to a pharmacy located remotely from said personal digital assistant over a communication link to be filled.

101. A computer program product, comprising:

a. a memory medium; and

b. a computer program stored on said memory medium, said computer program containing instructions for interrogating databases remotely located from a computer running said computer program expected to contain information about a patient based on a patient's relationship with the provider of that database; and for assembling patient information into a chronologically current version of said patient's medical history.

102. A computer program product, comprising:

a. a memory medium; and

b. a computer program stored on said memory medium, said computer program containing instructions for implementing a graphical user interface permitting capture of prescription information and providing access to all of (1) information about a patient's medical history, (2) information about therapeutic agents and (3) information about individual prescriber activity, wherein the information is obtained from one or more databases located remotely from a computing device running said computer program.